§170.315(e)(1) View, download, and transmit to 3rd party

2015 Edition Cures Update CCG

Version 1.0 Updated on 06-15-2020

Revision History

Version #	Description of Change	Version Date
1.0	Initial Publication	06-15-2020

Regulation Text

Regulation Text

§ 170.315 (e)(1) *View, download, and transmit to 3rd party—*

(i) Patients (and their authorized representatives) must be able to use internet-based technology to view, download, and transmit their health information to a 3rd party in the manner specified below. Such access must be consistent and in accordance with the standard adopted in § 170.204(a)(1) and may alternatively be demonstrated in accordance with the standard specified in § 170.204(a)(2).

(A) *View*. Patients (and their authorized representatives) must be able to use health IT to view, at a minimum, the following data:

(1) The data classes expressed in the standard in § 170.213 (which should be in their English (i.e., non-coded) representation if they associate with a vocabulary/code set), and in accordance with § 170.205(a)(4) and (a)(5), and paragraphs (e)(1)(i)(A)*(3)(i)* through *(iii)* of this section, or

(2) The Common Clinical Data Set in accordance with § 170.205(a)(4) and paragraphs (e)(1)(i)(A)(*3*)(*i*) through (*iv*) of this section for the period until May 2, 2022.

(3) The following data classes:

(i) Assessment and plan of treatment. In accordance with the "Assessment and Plan Section (V2)" of the standard specified in § 170.205(a)(4); or in accordance with the "Assessment Section (V2)" and "Plan of Treatment Section (V2)" of the standard specified in § 170.205(a)(4).

(ii) Goals. In accordance with the "Goals Section" of the standard specified in § 170.205(a)(4).

(iii) Health concerns. In accordance with the "Health Concerns Section" of the standard specified in § 170.205(a)(4).

(iv) Unique device identifier(s) for a patient's implantable device(s). In accordance with the "Product Instance" in the "Procedure Activity Procedure Section" of the standards specified in § 170.205(a)(4).

(4) Ambulatory setting only. Provider's name and office contact information.

(5) Inpatient setting only. Admission and discharge dates and locations; discharge instructions; and reason(s) for hospitalization.

(6) Laboratory test report(s). Laboratory test report(s), including:

(i) The information for a test report as specified all the data specified in 42 CFR 493.1291(c)(1) through (7);

(ii) The information related to reference intervals or normal values as specified in 42 CFR 493.1291(d); and

(iii) The information for corrected reports as specified in 42 CFR 493.1291(k)(2).

(7) Diagnostic image report(s).

(B) *Download.*

(1) Patients (and their authorized representatives) must be able to use technology to download an ambulatory summary or inpatient summary (as applicable to the health IT setting for which certification is requested) in the following formats:

(i) Human readable format; and

(ii) The format specified in accordance to the standard specified in § 170.205(a)(4) following the CCD document template.

(2) When downloaded according to the standard specified in § 170.205(a)(4) following the CCD document template, the ambulatory summary or inpatient summary must include, at a minimum, the following data (which, for the human readable version, should be in their English representation if they associate with a vocabulary/code set):

(i) Ambulatory setting only. All of the data specified in paragraph (e)(1)(i)(A)(*1*), (*2*), (*4*), and (*5*) of this section.

(ii) Inpatient setting only. All of the data specified in paragraphs (e)(1)(i)(A)(*1*), and (*3*) through (*5*) of this section.

(3) Inpatient setting only. Patients (and their authorized representatives) must be able to download transition of care/referral summaries that were created as a result of a transition of care (pursuant to the capability expressed in the certification criterion specified in paragraph (b)(1) of this section).

(C) *Transmit to third party.* Patients (and their authorized representatives) must be able to:

(1) Transmit the ambulatory summary or inpatient summary (as applicable to the health IT setting for which certification is requested) created in paragraph (e)(1)(i)(B)(*2*) of this section in accordance with both of the following ways:

(i) Email transmission to any email address; and

(ii) An encrypted method of electronic transmission.

(2) Inpatient setting only. Transmit transition of care/referral summaries (as a result of a transition of care/referral as referenced by (e)(1)(i)(B)(*3*)) of this section selected by the patient (or their authorized representative) in both of the ways referenced (e)(1)(i)(C)(*1*)(*i*) and (*ii*) of this section).

(D) *Timeframe selection*. With respect to the data available to view, download, and transmit as referenced paragraphs (e)(1)(i)(A), (B), and (C) of this section, patients (and their authorized representatives) must be able to:

(1) Select data associated with a specific date (to be viewed, downloaded, or transmitted); and

(2) Select data within an identified date range (to be viewed, downloaded, or transmitted).

(ii) *Activity history log.*

(A) When any of the capabilities included in paragraphs (e)(1)(i)(A) through (C) of this section are used, the following information must be recorded and made accessible to the patient (or his/her authorized representative):

(1) The action(s) (*i.e.*, view, download, transmission) that occurred;

(2) The date and time each action occurred in accordance with the standard specified in § 170.210(g);

(3) The user who took the action; and

(4) Where applicable, the addressee to whom an ambulatory summary or inpatient summary was transmitted.

(B) [Reserved]

Standard(s) Referenced

Paragraph (e)(1)(i)

§ 170.204(a)(1) Web Content Accessibility Guidelines (WCAG) 2.0, Level A Conformance

§ 170.204(a)(2) WCAG 2.0, Level AA Conformance

§ 170.205(a)(4) HL7 Implementation Guide for CDA Release 2 Consolidation CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use Release 2.1 C-CDA 2.1 with Errata, August 2015, June 2019 (with Errata)

§ 170.205(a)(5) Health Level 7 (HL7®) CDA R2 IG: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2, October 2019, IBR approved for § 170.205(a)(5)

Paragraph (e)(1)(i)(A)

§ 170.213 United States Core Data for Interoperability (USCDI)

Laboratory test report(s):

i. The information for a test report as specified all the data specified in 42 CFR 493.1291(c)(1) through (7);
   1. For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number.
   2. The name and address of the laboratory location where the test was performed.
   3. The test report date.
   4. The test performed.
   5. The specimen source, when appropriate.
   6. The test result and, if applicable, the units of measurement or interpretation, or both.
   7. Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

ii. The information related to reference intervals or normal values as specified in 42 CFR 493.1291(d) – Pertinent “reference intervals” or “normal” values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

iii. The information for corrected reports as specified in 42 CFR 493.1291(k)(2) – When errors in the reported patient test results are detected, the laboratory must do the following: Issue

corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results.

Paragraph (e)(1)(i)(B)

§ 170.213 United States Core Data for Interoperability (USCDI)

§ 170.205(a)(4) HL7® Implementation Guide for CDA Release 2 Consolidation CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use Release 2.1 C-CDA 2.1, August 2015, June 2019 (with Errata)

§ 170.205(a)(5) Health Level 7 (HL7®) CDA R2 IG: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2, October 2019, IBR approved for § 170.205(a)(5)

Laboratory test reports:

i. The information for a test report as specified all the data specified in 42 CFR 493.1291(c)(1) through (7) –
   1. For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number.
   2. The name and address of the laboratory location where the test was performed.
   3. The test report date.
   4. The test performed.
   5. Specimen source, when appropriate.
   6. The test result and, if applicable, the units of measurement or interpretation, or both.
   7. Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

ii. The information related to reference intervals or normal values as specified in 42 CFR 493.1291(d) – Pertinent “reference intervals” or “normal” values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

iii. The information for corrected reports as specified in 42 CFR 493.1291(k)(2) – When errors in the reported patient test results are detected, the laboratory must do the following: Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results.

Paragraph (e)(1)(i)(C)

Please refer to the standards required for § 170.315(d)(9) “trusted connection” for the encrypted method of electronic transmission.

Paragraph (e)(1)(ii)

§ 170.210(g) *Synchronized clocks*. The date and time recorded utilize a system clock that has been synchronized following (RFC 1305) Network Time Protocol or (RFC 5905) Network Time Protocol Version 4

Certification Companion Guide: View, download, and transmit to 3rd party

This Certification Companion Guide (CCG) is an informative document designed to assist with health IT product development. The CCG is not a substitute for the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program (ONC Cures Act Final Rule). It extracts key portions of the rule’s preamble and includes subsequent clarifying interpretations. To access the full context of regulatory intent please consult the ONC Cures Act Final Rule or other included regulatory reference. The CCG is for public use and should not be sold or redistributed.

Link to Final Rule Preamble

Edition Comparision	Gap Certification Eligible	Base EHR Definition	In Scope for CEHRT Definition
Revised	No	Not Included	Yes

Certification Requirements

Privacy and Security: This certification criterion was adopted at § 170.315(e)(1). As a result, an ONC-ACB must ensure that a product presented for certification to a § 170.315(e) “paragraph (e)” criterion includes the privacy and security criteria (adopted in § 170.315(d)) within the overall scope of the certificate issued to the product.

- The privacy and security criteria (adopted in § 170.315(d)) do not need to be explicitly tested with this specific paragraph (e) criterion unless it is the only criterion for which certification is requested.
- As a general rule, a product presented for certification only needs to be tested once to each applicable privacy and security criterion (adopted in § 170.315(d)) so long as the health IT developer attests that such privacy and security capabilities apply to the full scope of

capabilities included in the requested certification. However, exceptions exist for § 170.315(e)(1) "VDT" and (e)(2) "secure messaging," which are explicitly stated.

Table for Privacy and Security

- If choosing Approach 1:
  - Authentication, access control, and authorization (§ 170.315(d)(1))
  - Auditable events and tamper-resistance (§ 170.315(d)(2))
  - Audit reports (§ 170.315(d)(3))
  - Automatic access time-out (§ 170.315(d)(5))
  - End-user device encryption (§ 170.315(d)(7))
  - Integrity (§ 170.315(d)(8))
  - Trusted connection (§ 170.315(d)(9)) must be explicitly demonstrated with this criterion.
  - Encrypt authentication credentials (§ 170.315(d)(12))
  - Multi-factor authentication (MFA) (§ 170.315(d)(13))
- If choosing Approach 2:
  - For each applicable P&S certification criterion not certified for Approach 1, the health IT developer may certify using system documentation which is sufficiently detailed to enable integration such that the Health IT Module has implemented service interfaces that enable the Health IT Module to access external services necessary to meet the requirements of the P&S certification criterion. Please see the ONC Cures Act Final Rule at 85 FR 25710 for additional clarification.

Design and Performance: The following design and performance certification criteria (adopted in § 170.315(g)) must also be certified in order for the product to be certified.

- When a single quality management system (QMS) is used, the QMS only needs to be identified once. Otherwise, when different QMS are used, each QMS needs to be separately identified for every capability to which it was applied.
- When a single accessibility-centered design standard is used, the standard only needs to be identified once. Otherwise, the accessibility-centered design standards need to be identified

for every capability to which they were applied; or, alternatively the developer must state that no accessibility-centered design was used.

- Consolidated Clinical Document Architecture (C-CDA) creation performance (§ 170.315(g)(6)) does not need to be explicitly tested with this criterion unless it is the only criterion within the scope of the requested certification that includes C-CDA creation capabilities. Note that the application of § 170.315(g)(6) depends on the C-CDA templates explicitly required by the C-CDA-referenced criterion or criteria included within the scope of the certificate sought. Please refer to the C-CDA creation performance Certification Companion Guide for more details.

Table for Design and Performance

- Quality management system (§ 170.315(g)(4))
- Accessibility-centered design (§ 170.315(g)(5))
- Consolidated CDA creation performance (§ 170.315(g)(6))

Technical Explanations and Clarifications

Content Required

Function	Both Care Settings	Ambulatory Setting	Inpatient Setting
View	○ USCDI (English/human readable) ○ Laboratory test report(s) ○ Diagnostic image report(s)	○ Provider name ○ Office contact information	○ Admission and discharge dates and locations ○ Discharge instructions ○ Reason(s) for hospitalization
Download and Transmit	○ Human readable summary and Continuity of Care Document	○ Human readable summary and CCD also contain:	○ Human readable summary and CCD also contain:

	(CCD) document template containing: • USCDI • Laboratory test report(s) • Diagnostic image report(s)	• Provider name • Office contact information	• Admission and discharge dates and locations • Discharge instructions • Reason(s) for hospitalization ○ Transition of care/referral summaries created as a result of a transition of care or referral (human readable and CCD)

Applies to entire criterion

Clarifications:

- The scope of this criterion is limited to the C-CDA Release 2.1 CCD document template. Health IT developers may choose to offer view, download, and transmit to 3rd party (VDT) capabilities for other C-CDA templates as appropriate for different care and practice settings, but the CCD document template is the mandatory minimum that must be supported for this criterion.
- In combination with the C-CDA R2.1 standard, developers certifying to the USCDI must follow the guidance and templates provided in HL7 CDA® R2 IG: C-CDA Templates for Clinical Notes R2 Companion Guide, Release 2, for implementation of the C-CDA Release 2.1 standard. For example, details on how to structure and exchange Clinical Notes are included in the C-CDA Companion Guide.
- "Patients (and their authorized representatives)" are defined as any individuals to whom the patient has granted access to their health information. [see also 80 FR 62658 and 77 FR 13720]
- The technology specifications should be designed and implemented in such a way as to provide maximum clarity to a patient (and their authorized representative) about what data

exists in the system and how to interpret it. We expect that health IT developers will make choices following design and usability best practices that will make it easier and clearer for patients to find and use their records. [see also 80 FR 62659]

- In order to mitigate potential interoperability errors and inconsistent implementation of the HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, Draft Standard for Trial Use, Release 2.1, ONC assesses, approves, and incorporates corrections as part of required testing and certification to this criterion. [see Frequently Asked Questions #51] Certified health IT adoption and compliance with the following corrections are necessary because they implement updates to vocabularies, update rules for cardinality and conformance statements, and promote proper exchange of C-CDA documents. There is a 90-day delay from the time the CCG has been updated with the ONC-approved corrections to when compliance with the corrections will be required to pass testing (i.e., C-CDA 2.1 Validator). Similarly, there will be an 18-month delay before a finding of a correction's absence in certified health IT during surveillance would constitute a non-conformity under the Program.

Paragraph (e)(1)(i)

Technical outcome – Patients (and their authorized representatives) can view, download, and transmit their health information to a 3rd party via internet-based technology consistent with one of the WCAG 2.0 Levels A or AA.

Clarifications:

- A Health IT Module must demonstrate compliance with the WCAG 2.0 Level A at minimum, and may alternatively demonstrate compliance in accordance with the standard specified in Level AA protocols. This information will be listed with the product as part of its Certified Health IT Product List (CHPL) listing. [see also 80 FR 62660]
- A Health IT Module does not need to support both WCAG 2.0 Levels.
- Documentation from a third party or self-attestation that provides independent evidence of conformance to WCAG Levels A or AA can expedite a NVLAP- accredited testing laboratory's review, but health IT still needs to be independently assessed by the testing laboratory for conformance according to the ONC test procedure. [see also 77 FR 54179]

Paragraph (e)(1)(i)(A)

Technical outcome – View:

The health IT must allow patients (and their authorized representatives) to view, at a minimum, the USCDI; laboratory test report(s); and diagnostic image reports. Additionally, patients (and their authorized representatives) must be able to view for specific settings:

- Ambulatory setting only – the provider's name and office contact information;
- Inpatient setting only – the admission and discharge dates and locations; discharge instructions; and reason(s) for hospitalization.

Clarifications:

- To meet the "view" requirement, the USCDI information should be made available in its human readable/English (i.e., non-coded) representation.
- Please refer to the standards required by the USCDI.
- Throughout this criterion, this requirement pertains to the diagnostic image report, not the image(s) itself. A diagnostic image report contains the consulting specialist's interpretation of image data conveying the interpretation to the referring/ordering physician and should become a part of the patient's medical record. Unstructured data for the interpretation text is acceptable for certification. [see also 80 FR 62659]
- Although Health IT Modules must allow the patient to download and transmit corrected reports in accordance with 42 CFR 493.1291(k)(2), there is no need to separately test for this capability to achieve certification for this criterion. The laboratory test report requirement is satisfied if the Health IT Module demonstrates that it can send a test report.

Paragraph (e)(1)(i)(B)

Technical outcome – Download:

- In general, health IT presented for certification must be capable of creating CCD documents in order to demonstrate compliance with this certification criterion specified in § 170.205(a)(4) and (5) following the CCD document template. [see also 80 FR 16850; 80 FR 62659; and 80 FR 62674]
- Ambulatory setting – Patients (and their authorized representatives) must be able to download a summary in both a human readable format and using the CCD document template of the Consolidated CDA Release 2.1. If the patient (or their authorized representative) chooses to download a summary using the CCD document template, the information must contain:
  - The USCDI Data Elements;
  - The provider's name and office contact information;

- Laboratory test report(s);
- Diagnostic image report(s).

- Inpatient setting –
  - Patients (and their authorized representatives) must be able to download a summary in both a human readable format and using the CCD document template of the Consolidated CDA Release 2.1. If the patient (or their authorized representative) chooses to download a summary using the CCD document template, the information must contain:
    - The USCDI Data Elements;
    - Admission and discharge dates and locations;
    - Discharge instructions;
    - Reason(s) for hospitalization;
    - Laboratory test report(s);
    - Diagnostic image report(s).
  - Patients (and their authorized representatives) must be able to download transition of care/referral summaries that were created for a transition of care. [see also Transitions of Care Certification Companion Guide]
- For both settings, if the patient (or their authorized representative) chooses to download a summary using the CCD document template, the human readable CCD must include data in their English (i.e., non-coded) representation if associated with a vocabulary or code set.

Clarifications:

- Health IT may demonstrate that it is capable of creating CCDs in one of two ways.
  - As a native capability that is part of the health IT presented for certification; or
  - Relying upon a separate source system to perform the CCD creation capability. In this latter case, the source system would be performing a required capability to demonstrate compliance with this certification criterion and would be bound to the issued certificate as "relied upon software." [see Relied Upon Software Guidance] If taking this approach, the Health IT Module must be tested with at least one relied upon software product.
- The "human readable" aspect of this provision can be satisfied using a style sheet associated with a document formatted according to the C-CDA as specified in § 170.205(a)(4) and (5) following the CCD document template. [see also 80 FR 62634]

- A hyperlink to the data alone cannot satisfy this provision. The patient (or their authorized representatives) must be able to download the data to meet this requirement. [see also 77 FR 54180]
- For inpatient setting only, patients (and their authorized representatives) must be able to download transition of care/referral summaries.
- Health IT Modules may include laboratory test reports and diagnostic image reports in the "Results" section of the CCD.
  - For laboratory test reports, the C-CDA can support this information in a structured way using the "Result Observation Template" in the "Results" section.
    - There is no need to test for sending a corrected laboratory report; this requirement is satisfied if the Health IT Module can demonstrate that it can send a laboratory test report. [see also 80 FR 62660]
  - The C-CDA can support the laboratory test reports data in a structured way using the "Result Observation Template" in the "Results" section. We recommend developers follow the best practices for use of the Result Observation Template per HL7 (e.g., HL7 Task Force Examples). [see also 80 FR 62660]
  - We recommend developers code laboratory test report data where possible and appropriate in anticipation that future certification will require more extensively coded laboratory test report data. [see also 80 FR 62660] For diagnostic image reports, unstructured data for the interpretation text is acceptable. [see also 80 FR 62659]
- The "inpatient setting only" provision at paragraph (e)(1)(i)(B)(*3*), which requires a Health IT Module to enable the download of transition of care/referral summaries created as a result of a transition of care, tests the functionality of supplying such previously created C-CDAs and not the content/conformance of the C-CDAs supplied.

Paragraph (e)(1)(i)(C)

Technical outcome – Transmit:

- For both settings, patients (and their authorized representatives) must be able to transmit the CCD summary created in provision (i)(B)(*2*) through both (1) email transmission to any email address; and (2) an encrypted method of electronic transmission.
- In addition, for the inpatient setting, patients (and their authorized representatives) must be able to select and transmit transition of care/referral summaries created for a transition of care through both (1) email transmission to any email address; and (2) an encrypted method of electronic transmission.

Clarifications:

- Please see the OCR Frequently Asked Questions for best practices regarding the use of email for transmitting health information: http://www.hhs.gov/ocr/privacy/hipaa/faq/health_information_technology/570.html.
- For the email option, the approach is to provide patients with a readily understood and convenient option to send their health information via email. Under current HIPAA regulations (45 CFR 164.524 and related guidance), patients may presently ask that their data be disclosed to them via unencrypted email. [see also 80 FR 62660]
- For the encrypted "transmit" option, we encourage developers to provide innovative options for individuals to easily and efficiently protect their health information based on generally available mechanisms for security and new advances in this area.
  - The second "transmit" option is subject to the 2015 Edition privacy and security certification framework, particularly the "trusted connection" certification criterion (§ 170.315(d)(9)).
  - Health IT developers have the flexibility to either establish an encrypted connection between two end points or, alternatively, secure the payload via encryption.
  - The Direct protocol remains an encouraged and viable method to meet the requirements of the encrypted "transmit" requirement.
- Transferring data to an electronic media like a USB drive or DVD does not constitute "electronic transmission" to meet this criterion. [see also 77 FR 54182]
- For the purposes of transmission, several methods are acceptable with respect to enabling patients to use this capability. The transmission capabilities could include the ambulatory or inpatient summary created as a file attachment or provide another way for the patient to access their ambulatory or inpatient summary after initiating a transmission, such as a link embedded to their ambulatory or inpatient summary. In either case, however, note that the transmission capability must be able to support transmitting CCD documents and human readable formatted documents.

Paragraph (e)(1)(i)(D)

Technical outcome – Timeframe Selection:

For all of the provisions in (i)(A), (i)(B), and (i)(C) (i.e. View, Download, and Transmit capabilities), patients and their authorized representatives must be able to select data associated with a specific date and select data within an identified time range.

Clarifications:

Timeframes

- This criterion has two timeframe filters that patients must be able to select and configure on their own (specific date and date range). We did not include the ability to select a specific data element category as part of this filtering requirement.
- There is no need to allow for selection of a specific time within in each date range. For example, “9/1/2015 to 10/1/2015” is sufficient, rather than “9/1/2015 at 9:00am to 10/1/2015 at 5:00pm.” However, health IT developers may choose to include additional functionality to make it easy for patients to locate the information they need.

Data Requirements

- Paragraph (e)(1)(i)(D) and its subsequent subparagraphs focus on "data." The scope of the information to be included in the timeframe selection for paragraphs (e)(1)(i)(A),(B), and (C) is focused on the data as laid out in (e)(1)(i)(A)(*1*) and (e)(1)(i)(A)(*3*) through (*7*), which are more than just the USCDI Data Elements.
- All referenced data in the specified range of the timeframe selection must be returned regardless of whether the data is contained in a C-CDA document or in an atomic form and parsed.
- Returning all data all the time regardless of a date selection or date range selection is non-conformant insofar as the technology is not demonstrating filtering by date range. The health IT developer must be able to demonstrate that filtering based on the two timeframes can be done properly.
- Filtering in terms of excluding certain data must be by timeframe pursuant to the two filtering functionalities.
  - We expect that the Health IT Module must be able to send, at a minimum, all required data for a specified date range(s). We acknowledge that there will be organizational policies and/or safety best practices that will dictate additional data to be sent and when data is considered complete and/or ready for being sent.
  - For a Date Range Filter associated with VDT a System Under Test can provide the patient with one or more C-CDA documents that contain the data that is appropriate for the date range.

Approach

- The date/date range filtering capability does not alone require the creation of new CCD documents to match the patient’s date or date range selection. Health IT is not expected to decompose, extract, and recompose the data from multiple CCD documents into a single

larger CCD reflective of the entire date/date range filter selected. Rather, existing/previously created CCD documents in the health IT could be returned in response to a date/date range filter request that the patient could then view, download, or transmit. In other words, the health IT would not be expected to reproduce duplicative copies of CCDs it already created as part of this criterion's conformance requirements in order to meet the date/date range filter requirement. Providing a list of the existing/previously created CCDs for that date or within the specified date range would be acceptable.

- However, to be clear, the practice of creating a new CCD is not prohibited and would have the positive effect of making discrete data available to the patient upon request.
- Health IT must separately demonstrate compliance with paragraphs (e)(1)(i)(B)(*3*) and (e)(1)(i)(C)(*2*) of this criterion. However, the data requirements of paragraph (e)(1)(i)(D) do not apply to "supplied" transition of care/referral summaries referenced in these paragraphs.

Paragraph (e)(1)(ii)

Technical outcome – Activity History Log:

For all of the provisions in (i)(A), (i)(B), and (i)(C) (i.e., View, Download, and Transmit capabilities), patients (and their authorized representatives) must be able to access information regarding the action (view, download, or transmit) that occurred, the date and time each action occurred using Network Time Protocol RFC 5905, the user who took the action, and the addressee to whom the summary was transmitted.

Clarifications:

- Health IT may meet this requirement if it is certified to the 2015 Edition "auditable events and tamper-resistance" certification criterion (§ 170.315(d)(2)) and these data are accessible by the patient (and their authorized representatives).
- The time period for which the activity log should be available is a policy determination that the organization who implements the health IT should make. Testing and certification will only test for the health IT's ability to create such a log. [see also 77 FR 54184]

Content last reviewed on June 22, 2020